

Institutional Review Board (IRB) Policies & Procedures Manual



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Recruitment: Methods

Purpose

This policy describes recruitment methods and provides guidance concerning the following:

1. Medical Record Screening
2. Introductory Material
3. Telephone Recruitment and Communication
4. Directed Advertisement
5. Online
6. Recruitment of Participants at non-BCH Institutes
7. Recruitment of Participants by a non-BCH Investigator
8. Follow-up and Opting-out
9. Recruitment Efforts That Are Not Allowed

Policy

There is no one method for recruitment. The particular context of a protocol, subject population, and procedures may call for different recruitment methods. Regardless of the method, all efforts must be taken to avoid any type of undue influence.

Additional policies related to recruitment include: **Recruitment: Responsibilities and Requirments** and **Recruitment: Special Circumstances**.

Procedures

The timing, location, method, and the individual performing the recruitment may all inadvertently influence a subject to agree to participate.

These guidelines assure the appropriate human subject research protections while allowing flexibility as to when and how subjects are recruited. If there are reasons to deviate from these practices, they should be addressed in the protocol and the IRB will review and approve them as appropriate. The types and methods of recruitment are approved on a protocol-by-protocol basis.

Medical Record Screening

Investigators who wish to query medical records in order to find potentially eligible subjects for recruitment are required to justify a waiver of HIPAA Authorization to review records for recruitment purposes. The protocol application includes specific questions in order to justify a waiver for the review of records.

Introductory Material

Providing Written Information Prior to Approaching a Potential Subject

Providing materials prior to being approached enables families to give informed consideration to participating in the study and allow them to be better prepared to ask questions when they are approached directly.

Whenever possible, the IRB recommends that potential subjects receive written information about a study prior to being approached in person. This is not always possible, as it may not be practical for some protocols.

Some examples include: a letter sent to a potential subject's home or through approved electronic means approved by the IRB, a pamphlet, or an information sheet that is presented to a potential subject at the start of a visit.

Criteria: Care Provider or Chair/Chief of a Department Signature

In general and whenever reasonably possible, after potential subjects have left BCH, the IRB requires that initial recruitment materials (i.e. letters, surveys, information sheets, etc.) to potential research subjects be signed/co-signed by a care provider known to the family or the Chair/Chief of a department with which the family is familiar.

If an investigator feels they cannot follow this guideline, they will need to provide a justification in detail within their protocol on why this is not possible.

Recommended elements:

- How the potential subject's name was obtained. For example, it should be indicated how and from where the list of names of potential subjects was generated.
- What information the investigator has obtained about the patient.
- When applicable, the fact that the medical record was *not* reviewed and what was *not* accessed.
- An acknowledgement of the family's status to discern if it is an appropriate time to recruit (i.e., death of child, stressful time, etc.).

Telephone Recruitment and Communication

Telephone recruitment can be acceptable. In most cases, the IRB will require introductory recruitment materials (see item 1: Introductory Material); however, there are limited situations when an initial call is acceptable.

Initial Phone Contact Requirements

It is important that subjects are aware that the call is a legitimate call from Boston Children's Hospital. The IRB requires that any initial phone contact for recruitment purposes be made on a Boston Children's Hospital telephone. The telephone must indicate that it is a Boston Children's Hospital on the caller ID

Established Relationship and Personal Phone Use

Once initial contact is made and you have established a relationship with the potential subject, it is acceptable to use other personal phones with the understanding of the following guidelines:

It is highly recommended that when using a personal phone, the *67 feature be utilized when placing the call to prevent the actual cell phone number from being displayed.

Recommendations:

1. In situations where there is concern that recipient phones will block all non-identified calls or the researcher wants the number to be displayed, subjects should be advised during the initial contact as to:
 - a. How they will be contacted and
 - b. By whom so they will recognize the calls.
2. It is important to remember to only use cell phones where appropriate confidentiality can be maintained. Calls should not be made in public locations where privacy cannot be maintained.

Directed Advertisement Placement

Advertisements that are to appear on television or other predominately public locations may be subject to review by the Public Affairs Office.

Online

Internet and Social Media:*

Internet and social media recruitment is subject to the same regulatory and ethical norms as traditional recruitment, including the requirements of prospective review and approval by an IRB compliance with all applicable federal and state laws, fair and equitable subject selection, respect for the privacy and other interests of potential participants, sensitivity to the norms and values of different communities, and consideration for the impacts of different recruitment techniques on public trust in the research enterprise

Investigators proposing internet social media recruitment should approach it in substantially the same way they do traditional recruitment methods. Investigators should:

- Ensure that social media recruitment methods comply with all pertinent laws and federal regulations, including HIPAA and HITECH.
- Ensure that proposed social media recruitment techniques comply with the policies and terms of use of the relevant websites
- Ensure that the proposed recruitment strategy:
 1. Is sensitive to the privacy of potential participants;
 2. Is respectful of the norms of the community being recruited; and
 3. Will not undermine public trust in the research enterprise, including via deceptive practices or lack of transparency.

*taken from Harvard Catalyst "The Use of Social Media in Recruitment to Research: A Guide for Investigators and IRBs"

The BCH IRB will work closely with the Social Media department at BCH to assure that all institutional policies are followed. Investigators may be instructed to contact the social media department as part of the IRB review and approval process

Clinical Trial Listings Websites

IRB review and approval of clinical trial listings on the internet are not required when the system format limits the information provided to basic trial information such as: the title, purpose of the study, protocol summary, basic eligibility criteria, study site location(s), and how to contact the site for further information.

Examples of clinical trial listing services that do not require IRB approval include the following: National Cancer Institute's Cancer Clinical Trial Listing (PDQ), Clinicaltrials.gov and the government-sponsored AIDS Clinical Trials Information Service (ACTIS).

When the opportunity to add additional descriptive information is allowed by the database system, IRB review and approval are required.

Recruitment of Participants at External non-BCH Institutions

Requests to post a notice on a bulletin board, leave pamphlets in a clinic/procedure/inpatient waiting area or have individuals distribute information regarding research conducted at an external non-BCH institution is permitted.

In these situations, a parent or child may read the information and decide whether he or she wishes to contact the BCH investigator. However it is necessary to assure that all policies regarding this type of recruitment are in accordance with the external institution. In addition this plan should be disclosed in the protocol application.

Recruitment of Participants at BCH for non-BCH Research

If a Boston Children's Hospital investigator is asked to participate in recruitment activities for a non-BCH Investigator, that consist of:

- Identifying eligible subjects or
- Assisting in recruiting procedures by discussing information about a study with a possible participant or
- Assisting in the informed consent process, or

A research protocol from the other institution must be reviewed and approved by the Boston Children's Hospital IRB or arrangements for a reliance agreement must be made.

This is necessary because a Boston Children's Hospital investigator is actively performing activities that may be viewed as "engagement" in human subject research. It is possible that Boston Children's Hospital will rely on another institution's IRB approval, however the IRB office must be notified to make this decision.

If activities are limited to solely distributing information about the research and it is up to the potential subject to contact the external investigator, BCH IRB approval is not required.

For more information, see the IRB policy: **Reliance Agreements**.

Follow-up and Participant Opt-Out

Follow-up

When a potential subject does not respond to the initial recruitment contact, it is highly recommended that follow-up contact be limited to three attempts. The IRB considers “contact” to include voice messages, emails, texts, etc.

When describing plans for contacting individuals multiple times in an effort to secure their enrollment into the study, it should be specified how many contact attempts will be made and the mode (i.e. voice messages, emails, texts, etc.).

If an investigator feels they cannot follow this guideline, they will need to provide a justification in detail within their protocol on why this is not possible for the intended study.

Opt-out Option

Potential subjects must be given the option to request no further contact.

It is suggested that a method to opt-out (i.e. mailing response card, telephone number, email address, etc.) be included with the recruitment effort for subjects to respond if they do not wish to be contacted further.

If a potential subject responds indicating they would like to opt-out, no further contact of that individual is to be attempted.

Recruitment Efforts That Are Not Allowed

Cold-Calling

The IRB does not consider “cold calling” an acceptable recruitment practice.

Cold-calling is the practice of investigators or research staff, unknown to the potential research subject, initiating contact with the potential subject based on their prior knowledge of private information.

In general surveys (i.e. telephone) may not be undertaken before recruitment information (i.e. letter, information sheet, etc.) is sent to potential subjects that enables them to decline participation/further contact. If there are reasons why this is not possible, they should be explained in the research protocol and approved by the IRB.

Financial Incentives and Sponsor Coupons

Financial Incentives: Finder’s Fees and Bonuses

Clinical research is an important component of Boston Children’s Hospital’s commitment to providing the best quality of care to its patients. In pursuing this commitment, house officers, staff, and other personnel are expected to assist investigators in the performance of clinical research.

The provision of a direct financial incentive to staff members or hospital personnel for enrolling a research subject may add a strong element of undue influence to the recruitment and consent processes. For this reason, under no circumstances may house officers, staff members, and hospital personnel be offered or accept a monetary “finder’s fee” or other incentive for recruiting

or referring subjects for a clinical investigation. House officers, staff, and BCH employees are expected to observe this policy as one of their routine responsibilities at BCH.

In addition, no investigator or their research staff may accept any type of payment to accelerate recruitment that is tied to the rate or timing of enrollment.

Sponsor Coupons

Compensation for participation in a trial offered by a sponsor to include a coupon good for a discount on the purchase price of the product once it has been approved for marketing is never allowed.

Related Content

IRB Policies

Recruitment: Responsibilities and Requirements

Recruitment: Special Circumstances

Reliance Agreements

Document Attributes

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